



# Patient Safety America Newsletter

May 2010

<http://PatientSafetyAmerica.com>

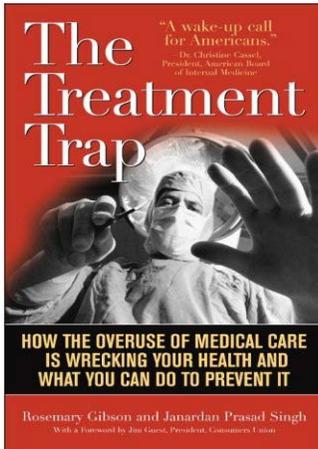
John T. James, Ph.D.

*Question: According to a recent report from the Agency for Healthcare Research and Quality, how much did the incidence of postoperative sepsis or blood stream infections change in 2007 in hospitals?  
a) decrease 4%    b) no change    c) increase 4%    d) increase 8%    e) increase 12%*

## Book Review: The Treatment Trap

By Rosemary Gibson and Janardan Prasad Singh

Ms. Gibson and Mr. Singh joined forces a few years ago to write a book about healthcare secrets called “The Wall of Silence” (November 2008 PSA Newsletter). Their most recent book, “The Treatment Trap,” builds on the first book by attacking the perverse monetary incentives in the American healthcare industry, and does it effectively through stories, interviews, and science.



Gibson and Singh use their first eight chapters to dissect the troubling facets of our healthcare industry. They survey expert voices from the past that have called for an end to overuse and misuse of medical care, and then the authors turn to contemporary experts to

characterize present misuse of healthcare. A human face is given to victims of that misuse through a collection of short stories. Gibson and Singh examine the motives of doctors that foster overuse of healthcare, noting that perverse motives are not always behind the overuse. It is natural to want to sell your product in an enthusiastic way. They lament the lost era when doctors took more time to know their patients. Modern medicine has become more about efficiency and bottom line than compassion and healing. We are warned to be wary of where we get healthcare advice – media healthcare news can be nothing more than an advertisement disguised as “exciting news.”

By Chapter 9, called “The Chapter You Won’t Want to Read,” the reader has been prepared for a series of true “Green Monster” stories. These chronicle the abuse of patients in order to meet the monetary needs of physicians and hospitals. The stories describe flat-out disgusting behavior.

The third part of the book describes ways patients have been suspicious of the medical advice they have been initially given, and this has ultimately paid off in less treatment and better outcomes. One story of a little girl who refused to have a tonsillectomy made me laugh out loud – you’ll see why. Next, an appeal is made to the provider community to “Do it with me not to me.”

The fourth part of the book speaks to solutions to the treatment trap, including individuals seeking to reduce costs by having inexpensive, but excellent care in other countries such as India. A late chapter purports to be a ten-step recovery plan, but it is too superficial for my liking. For example, trying to find the ten things we should stop doing is not as simple as the authors suppose. The target should be to determine the ten or more things that are overused and clearly define the cases where their use is appropriate.

An example of overuse I would cite is angioplasty (placement of cardiac stents), a procedure that is grossly overused by invasive cardiologists, but does have great value in a limited set of patients. The authors suggest that Medicare should quit paying for things that don’t work, and I heartily agree. One of the ten steps to recovery is to find out what does work. This is a complex undertaking (see next story), and even when solid evidence exists for what works, getting doctors to follow the evidence can be a challenge.

The authors close with a chapter dedicated to ways to protect oneself from becoming a victim of the “Green Monster.” By describing actions an assertive patient must do, we are once again faced with the shortcomings of American healthcare: it’s about getting your money, turning well-insured patients into cash cows, poor quality control, media “news” run amuck, failure to follow scientific evidence, pressure on patients

to proceed with treatment, withholding information from patients, lack of integrated care, inaccurate medical records, perverse financial incentives, and lack of preventive care. Ugh!

I like this book and I like the way it is written. It has a few weaknesses, such as not explicitly mentioning evidence-based guidelines as the hallmark of good medical care, but overall it is an easy, disturbing, and succinct treatment of our sick healthcare industry. It would make a good read for college students taking a required health class. I grew up trusting healthcare. It's time we raise a generation that knows better. **4 ½ stars**

## *Comparative Effectiveness Research*

Sooner or later you as a patient will be in the hands of healthcare. You may have to make some difficult choices. How will you do that? Will your doctor know how to guide you to the right choices without bias? Unfortunately, for many illnesses no one knows the right decisions. This is because the massive healthcare research community in the U.S. has neglected comparative effectiveness research (CER).

One scientific study I want to summarize defined CER as “the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions.”<sup>1</sup> An editorial on CER defined it as “patient centered health research.”<sup>2</sup> As a simple-minded patient I'd like to know why medical research that is in my best interest has been so neglected. Fortunately, this recently changed when Congress passed a \$1.1 billion bill to support CER.

A study by two MDs published in the *JAMA* systematically investigated hundreds of studies of the CER of medications.<sup>1</sup> The studies were published in 2008 and 2009 in six high-impact, general medical journals. The investigators identified important shortcomings in their collection of studies. Only 11% compared drug and non-drug treatment strategies, and only 18% paid any attention to the safety of the drugs. Cost was rarely (2%) a factor considered in the studies. Without cost-effectiveness data our need to manage healthcare dollars is compromised. I have to wonder if there is an unspoken conspiracy here to keep patients and their physicians from getting the data they need to make fully-informed choices. If I want to sell a drug, do I really want everyone knowing all of its safety problems?



If I want to make plenty of money, do I really want someone comparing the cost-effectiveness of my drug to all others with the same medical purpose?

An editorial by two other MDs attempted to outline a pathway to improve CER to the benefit of patients and the physicians that help with patient decisions.<sup>2</sup> They note that too many decisions must be made without reliable information. Having survived a bout with prostate cancer in 2008, I can attest to the lack of CER for this common form of cancer. I had to make decisions that were far too arbitrary, and the medical material I was given by my urologist was outdated and not very helpful.

One part of this editorial I especially liked was the declaration that the results of CER must be kept in an inventory where researchers, clinicians, and *patients* can gain access. Clearly, the database useful to medically-trained people will need to be more sophisticated than the information available to patients, but patients *will* have access. Scientists completing their research for this database should be required to write a summary suitable for patients to read and understand. In addition, video presentations should be readily available for patients to hear a description of the database pertaining to a given illness or treatment. This will have two positive effects. The researchers will be reminded who they are working for, and patients will develop more trust in medical researchers.

## *The Patient's Voice in Drug Safety*

A perspective article in the *New England Journal of Medicine* by an MD emphasized the need to learn about the adverse effects of a drug from patients that are taking the drug.<sup>3</sup> The author reports data gathered from 467 patients that made more than 4,000 hospital visits during which they were evaluated by the Health Outcomes Group at Memorial Sloan-Kettering Cancer Center. Traditionally, the adverse effects of drugs have been reported by clinicians administering the drug. For this study the investigators asked the patients to report adverse symptoms directly to the Group and independently of clinicians.

The investigators compared six symptoms (fatigue, appetite loss, nausea, vomiting, diarrhea, constipation) as reported by patients and clinicians. The reporting levels stabilized after about 10 months for each drug. Patients had much higher reporting levels



than clinicians. For example, at the 10-month mark about ¾ of patients reported fatigue, whereas, the clinicians reported that about ½ their patients had fatigue. Perhaps the largest difference was in the reporting of appetite loss. The clinicians reported this effect in about 1 in 20 patients, whereas almost a third of the patients reported that they experienced appetite loss.

The author asked why patient reporting of adverse effects is not standard practice during drug evaluations. He then gave several possible answers, none of which were “insurmountable.” In my opinion the barriers the author listed were in the category of weak excuses to avoid change. He concluded that using data from patient questionnaires could identify worrisome adverse effects earlier in drug development and ultimately lead to safer drugs. **The next time a doctor prescribes a drug to you, especially if it is a new drug ask him how you can report side effects to the FDA. The answer he gives could be fascinating.**

### *To Err is Human-What’s Next?*

We all know that humans make mistakes. In medicine mistakes can kill people. How does a just culture deal with the balance between accountability for an error (punishment) and a non-judgmental response? Two MDs deal with this question in a commentary called “Getting it right when things go wrong.”<sup>4</sup> The Agency for Healthcare Research and Quality has identified three types of human error: slips, at-risk behavior, and reckless behavior. Enter the concept of a “just culture.” Should justice include “retributive justice?” Should the “restorative” model be used? Under the first model, at-risk behavior could evoke a temporary loss of hospital privileges (retribution). Under the restorative model the same level of offense would elicit required training, at

least for an initial infraction.



I work in a culture (human spaceflight) where unsafe practices can be reported without any fear of retribution, so I am aware of the benefits of a non-judgmental culture. I

am also aware that we still fail and people (astronauts) lose their lives. We have no opportunity to hide our worst errors. We also make it a point to learn from near misses, and we also practice full transparency and outside scrutiny; none of these is a characteristic of our American medical culture.

The authors point out that when a physician makes an error that harms someone, they are likely to suffer from their mistake, leading to dread, anger, and defensiveness. One of the most difficult things in life is living with deep guilt, and finding a way to forgive oneself can take years or may never happen. The writers suggest asking three crucial questions when a physician has made an error: 1) was the standard of care met, 2) will he accept the lessons that were learned, and 3) will he maintain patient contact and bring full disclosure?

I enjoyed the thoughtful commentary of these physicians, and they can only do so much in a brief paper; however, there were some concerns that came to my mind from a patient’s view point. I want to consider three rather scattered topics: slips, system failures, and standard of care.

Humans slip even when preparations are ideal. But if a slip is due to fatigue (say a resident in his 28<sup>th</sup> hour of work) or a surgeon is operating when he is impaired by alcohol or drugs, then the slip becomes “at risk” behavior. My point is that the reason for any slip must be discerned to determine if a preventable error has occurred. Of course patterns of slips must be identified in case there is a root cause that needs attention.

The authors suggest many errors are system failures. I would suggest that some major system failures rest at the foot of the physician community. For example, the way physicians demonstrate competency leaves me with no confidence in their medical knowledge being current (see the next article). Continuing medical education, where it is required by states, lacks focus on the physician’s specialty and is not rigorously assured by state regulations (at least in Texas). Thus, if a doctor makes a diagnostic error due to failure to remain current in his field and a patient dies (roughly 50,000 do each year), is it a system failure or a personal failure?

“Standard-of-care” is one of those topics that cause me to cry-out in frustration. In Texas “standard-of-care,” according my experience with the Texas Medical Board is a highly subjective concept that seems to be more akin to “trying hard.” It does not matter if widely-published, national guidelines developed by experts are ignored or an obvious diagnosis missed; if the doctor seemed to try hard then he has met the Texas standard of medical care.

### *Does your Doctor Know?*

Keeping up with new medical discoveries and applying them effectively to patients is a daunting task. One might suppose that physicians have developed an efficient and comprehensive way to capture new medical

discoveries and disseminate these into the clinician community. You would be wrong, perhaps dead wrong. In a series of opinions from physicians published in the *New England Journal of Medicine* the woefully inadequate way physicians continue to learn is inadvertently revealed. That is not the intention of the opinions, but a little inspection discloses the problems. Besides their ongoing experience base, there are two major ways doctors can acquire new knowledge. The first of these is state-mandated continuing medical education (CME). Among the states, the mandated number of hours per year ranges from zero to fifty, but none is specifically required in the physician's declared specialty. Is it any wonder that one of the articles, citing



three studies, observes that CME does not improve physician performance or knowledge.<sup>5</sup>

The second way that physicians acquire new knowledge outside their practice experience is through board certification and periodic recertification. Surprisingly, a physician does not have to be board

certified to represent himself as a specialist to the public. In addition, there are many second-rate board certifications appearing that are generally regarded as unable to give any assurance of competency.

What about the traditional and well-respected boards, such as those under the purview of the American Board of Medical Specialties. Can certification by these boards assure physician competency? There are two cases. One applies to physicians given limited certificates after 1990. They must periodically recertify. For example, internists must recertify every decade. Unfortunately, medical knowledge grows so quickly that information more than 5 years old may be well out of date. This approach is better than nothing, but it is clearly inadequate to ensure that your internist is up to speed on the latest findings.

Physicians that were board certified before 1990 trouble me most as a patient. These physicians were given lifetime certificates. This means that they do not have to recertify to continue to represent themselves to the public as board certified. However, these specialists can choose to voluntarily participate in maintenance of certification (MOC). This choice prompted the series I am reviewing here.

Two MDs make the case that internists with lifetime certificates should voluntarily recertify.<sup>5</sup> They

view MOC as a superior process to CME and cite several studies linking MOC to better physician performance. They note that physicians' ability to self assess their learning needs is poor. Barriers to voluntary participation include costs and time. Of course, the fear of failure is another barrier. They note that there are flaws in the testing, but that these can be reduced by feedback from participants.

Three other MDs argue that a physician with lifetime certification should not voluntarily recertify.<sup>6</sup> They note that very few physicians choose to recertify, which they interpret to mean that the specialists think the process is irrelevant to their practice. I would argue that it is more likely the cost, time, and fear-of-failure that limit voluntary MOC. They argue that there is not "definitive evidence" that recertification benefits patient care. They further argue that the recall of facts on the closed examination does not make an improvement in patient care.

As a patient I feel that physicians should demonstrate some level of competency through recertification or be required to disclose to all their patients when the last time was that they were subjected to a competency assessment. You might like to know that almost  $\frac{3}{4}$  of cardiologists in a national survey admitted that they had not been evaluated for competency in the past 3 years.<sup>7</sup>

## References

- 1) Hochman, M and D McCormick. Characteristics of published comparative effectiveness studies of medications. *JAMA* 303:951-958, 2010
- 2) Conway, PH and C Clancy. Charting a path from comparative effectiveness funding to improved patient-centered health care. *JAMA* 303:985-986, 2010
- 3) Basch, E. The missing voice of patients in drug-safety reporting. *N Engl J Med.* 362:865-869, 2010
- 4) Pettker, CM and EF Funai. Getting it right when things go wrong. *JAMA* 303:977-978, 2010
- 5) Levinson, W and TE King, Jr. Enroll in the MOC program as currently configured. *N Engl J Med* 362:949-950, 2010
- 6) Goldman, L, AH Goroll, and B Kessler. Do not enroll in the current MOC program. *N Engl J Med* 362:950-952, 2010
- 7) Campbell, EG, S Regan, RL Gruen, et al. Professionalism in medicine: Results of a national survey of physicians. *Ann Intern Med* 147:795-802, 2007
- 8) California Healthline, April 14, 2010

Answer to question this month: d) increase 8%<sup>8</sup> (note: postoperative pneumonia *decreased* 12% ☺)